(c) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER), and the Director and Deputy Director, Office of Compliance, CDER.

[48 FR 56948, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 57 FR 40317, Sept. 3, 1992]

§ 5.56 Recall authority.

The following officials, for medical devices assigned to their respective organizations, are authorized to perform all of the recall functions under section 518(e) of the Federal Food, Drug, and Cosmetic Act, which have been delegated to the Commissioner of Food and Drugs:

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(b) The Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(c) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER), and the Director and Deputy Director, Office of Compliance, CDER.

(d) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Compliance, CBER.

[56 FR 51170, Oct. 10, 1991, as amended at 57 FR 40317, Sept. 3, 1992]

§ 5.57 Temporary suspension of a medical device application.

The following officials for medical devices assigned to their respective organizations are authorized under section 515(e) of the Federal Food, Drug, and Cosmetic Act, to determine that there is reasonable probability that continuation of the distribution of a device under an approved application would cause serious adverse health consequences or death, and upon making such a determination, to issue an order to temporarily suspend the approval of an application:

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(b) The Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(c) The Director, Deputy Director, and Associate Director, Office of Device Evaluation, CDRH.

(d) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER); the Director, Pilot Drug Evaluation Staff, CDER; the Directors and Deputy Directors of the Offices of Drug Evaluation I and Drug Evaluation II, CDER; the Director and Deputy Director, Office of Generic Drugs, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

(e) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Compliance, CBER.

[56 FR 51170, Oct. 10, 1991, as amended at 57 FR 40317, Sept. 3, 1992]

§ 5.58 Orphan products.

(a) The Director, Office of Orphan Products Development, Office of the Commissioner, is authorized to issue notices, and amendments thereto, inviting sponsorship for orphan products (human and animal drugs, biological products, and medical devices) and submission of:

(1) Notices of claimed investigational exemption for a new drug or new drug applications;

(2) Notices of claimed investigational exemption for a new animal drug or new animal drug applications;

(3) Applications for establishment and product licenses for biological products; or

(4) Applications for an investigational device exemption or premarket approval applications for medical devices, as appropriate.

(b) The Director, Office of Orphans Products Development, Office of the Commissioner, is authorized:

(1) To determine whether there is reason to believe that a drug is a drug for a disease or condition that is rare in the United States under section 525(a) of the Federal Food, Drug, and Cosmetic Act (the act) and to designate such drug as a drug for a rare disease or condition under section 526(a) of the act.

(2) To issue holders of approved applications or licenses notice and